PATENT SPECIFICATION 986,28

NO DRAWINGS.

986,284

Date of Application and filing Complete Specification:
June 6, 1962. *No. 21932/62.*

Application made in United States of America (No. 146,021) on June 7, 1961.

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ERRATA

SPECIFICATION NO. 986,284

Amendment No. 1

Page 1, line 27, *for* "section" *read* "selection".

Page 3, line 115, *for* "1%" *read* "10%".

Page 5, line 15, *for* "123-38°" *read* "128-38°".

THE PATENT OFFICE,
24th June, 1965

D 40571

patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to tablets characterized by a thin film coating of a water-permeable, plastic composition and to the method of making such coated tablets. The invention also relates to a thin, water-permeable tablet coating and to a liquid composition useful for laying down the aforementioned film.

In recent years, plastics have found their way into the tablet coating art but up to the present time only a limited number of synthetic resins have been found useful for coating medicinal tablets. Due to the fact that only a few resins are water-permeable and among those only a few are inert to the human body absorbing such materials, the section of synthetic resins for tablet coating has been extremely limited. The resins heretofore proposed as useful, however, are deficient in various respects. In spite of being ... leaves something to be desired, and, if the core is acidic, the cellulose acetate phthalate becomes less soluble in water ond therefore in the digestive tract. This stems from the fact that cellulose acetate phthalate has a significant percentage of free carboxy groups which also have certain other undesirable properties.

It is therefore an object of the present invention to provide a tablet which is coated with a thin plastic film which is substantially water-permeable. It is another object of the invention to provide a tablet coated with a synthetic, water-permeable resin inert to gastrointestinal juices. It is a further object of the present invention to provide a tablet coating which permits rapid release of the active ingredient from the tablet core. A still further object of the present invention is the provision of a tablet coating stable to climatic influences such as high humidity and high temperature as encountered in tropical climates. It is another object of the inven-

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Int. Cl.:—C 08 f //A 61 k, C 08 g.

COMPLETE SPECIFICATION.

Coating Composition.

We, ABBOTT LABORATORIES, a Corporation organized and existing under the laws of the State of Illinois, United States of America, of 14th Street and Sheridan Road, North Chicago, County of Lake, State of Illinois, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to tablets characterized by a thin film coating of a water-permeable, plastic composition and to the method of making such coated tablets. The invention also relates to a thin, water-permeable tablet coating and to a liquid composition useful for laying down the aforementioned film.

In recent years, plastics have found their way into the tablet coating art but up to the present time only a limited number of synthetic resins have been found useful for coating medicinal tablets. Due to the fact that only a few resins are water-permeable and among those only a few are inert to the human body absorbing such materials, the section of synthetic resins for tablet coating has been extremely limited. The resins heretofore proposed as useful, however, are deficient in various respects. In spite of being inert to the digestive tract of the human body, some of these earlier proposed resins are quite reactive and cannot be used universally for any active drug due to reactivity of the resin with the active drug or core of the tablet. For instance, if the core is alkaline, adherence of the previously proposed cellulose acetate phthalate resin to the tablet leaves something to be desired, and, if the core is acidic, the cellulose acetate phthalate becomes less soluble in water ond therefore in the digestive tract. This stems from the fact that cellulose acetate phthalate has a significant percentage of free carboxy groups which also have certain other undesirable properties.

It is therefore an object of the present invention to provide a tablet which is coated with a thin plastic film which is substantially water-permeable. It is another object of the invention to provide a tablet coated with a synthetic, water-permeable resin inert to gastrointestinal juices. It is a further object of the present invention to provide a tablet coating which permits rapid release of the active ingredient from the tablet core. A still further object of the present invention is the provision of a tablet coating stable to climatic influences such as high humidity and high temperature as encountered in tropical climates. It is another object of the inven-

tion to provide an inexpensive and efficient method of coating tablets which will materially shorten the tablet coating cycle.

According to the present invention there is provided a coating composition for tablets, the coating composition containing as essential ingredients:—

(a) A physiologically acceptable substance being a water-soluble or water-dispersible organic compound with a melting point of at least 45°C, selected from poly (ethylene glycol), glyceryl monostearate and diglycol stearate,

(b) A film forming resin selected from poly (methylstyrene), methylstyrene/acrylonitrile copolymers, poly (vinyl butyral), poly (vinyl chloride), pentaerythritol and alkyd esters of rosin, pentaerythritol esters of modified rosins, and terpene-modified alkyd resins; and

(c) An organic solvent system boiling below 85°C.

The use of a solvent system boiling below 85°C. produces shorter drying periods. Most commonly, acetone ethanol, methyl ethyl ketone, methylene chloride or mixtures thereof, are used. Several other ingredients may be added to the previously named essential components in order to enhance the properties of the coating obtained from the composition. Among the more important of these additional materials are dyes, pigments, water-insoluble waxes, plasticising agents, wetting agents, drying agents, flavoring agents.

One of the hard, water-soluble or water-dispersible, waxlike substances to which the invention pertains is a poly(ethylene glycol) of a melting point of at least 45° C. However, it is to be understood that similar physiologically acceptable materials of this class can be substituted therefor. Among the water-dispersible waxes which may be used as additives are glyceryl monostearate, diglycol/stearate, etc.

Among the coloring agents which may be used in the practice of this invention are any of the non-toxic dyes, lakes, and pigments which have been certified for use in the food, drug and cosmetics industries, e.g. D & C Red #21, yellow hydrated iron oxide, D & C Red #3, etc. Among the water-insoluble waxes which are suitable as additives are beeswax, lanolin, stearic acid, cocoa butter, and cetyl alcohol. As plasticizing agents, castor oil, mineral oil, corn oil, sesame oil, propylene glycol and the like may be used. If desired, a drying oil such as soy bean oil or the like, or a surface active agent such as the polyoxyethylene sorbitan derivatives or the sulfated fatty alcohols of the Duponol type may be added. In the case of D & C dyes, it may be necessary to deposit the dye on a pharmaceutically acceptable carrier such as aluminum hydroxide.

When the foregoing composition is applied to tablets in the manner hereinafter described, it is possible to provide a suitable coating for a tablet or the like with the use of relatively few coats or applications of the coating material, producing a thin, flawless coat over the tablet core.

In this aspect the present invention provides a tablet having as a coating material a thin film of a plastic coating composition consisting essentially of the water-permeable combination of a physiologically acceptable substance selected from poly (ethylene glycol), glyceryl monostearate and diglycol stearate and a film-forming resin selected from poly (methylstyrene), methylstyrene/acrylonitrile copolymers, poly (vinyl butyral), poly (vinyl chloride, pentaerythritol and alkyd esters of rosin, pentaerythritol esters of modified rosins, and terpene-based alkyd resins.

Another highly important advantage of this invention is that the coating composition described above can be applied from organic solvent systems of low boiling point, reducing the drying period between coats substantially. Hence, it is possible to completely coat a tablet in a matter of minutes where prior practices have required four to six days to obtain a suitable coating. Another advantage of the present invention is the fact that the synthetic resins which form a substantial part of the present coating composition are highly inert to the gastrointestinal juices as well as the reactive entities in the tablet core. No interaction between these resins and the drug occurs. This lessens the probability of chemical incompatabilities being encountered, and decreases the problems encountered in the actual physical application of the coating to the core. The presently claimed coating compositions also provide rapid disintegration so that the active drug is available for digestion almost immediately after ingestion.

When the coating composition claimed herein is applied without coloring agent, a pleasing white tablet is obtained. The transparent coating may be rendered opaque by the addition of a quantity of an opaqueing agent or a white pigment such as titanium dioxide, if desired. The invention is also most highly suited to the application of colored film coating of the type described in which a small quantity of a suitable coloring agent such as dyes, lakes, or pigments is incorporated into the coating solution prior to application on the tablets. In this manner, a highly pleasing colored appearance is given to the tablets and the tablets are regarded as elegant in the terms of the trade. A tablet coated according to the practice of this invention is considerably smaller in size than one coated by the heretofore conventional sugar coating procedure, and the small

tablet is more acceptable because it can be swallowed more easily. The film of this invention very effectively coats the tablets so but at the same time, distinctive markings that no unpleasant taste can be perceived, punched into the tablet core will show through very clearly and are readily discernible on the surface. Since no sugar coating is required in order to give these tablets elegance, the taste appeal leading sometimes to accidental ingestion of tablets is substantially minimized. Also, the absence of sugar is a distinct advantage in those instances where it is desirable to limit caloric intake. A sweetening or flavoring agent may be added, of course, where desired.

It is preferred to use between 14% and 20% w/v of the hard, water-soluble or water-dispersible, waxilke substance in making up the fluid coating composition for application to tablets. Likewise, 4% 7% w/v of the film-forming resin is desirable. The water insoluble waxy adjuvant is not used in a concentration greater than 5% w/v and a plasticizing agent is used in concentrations of from 1% to 5% w/v. In this manner, the finished tablet coating contains between about 66% and about 84% by weight of the hard, waxy, water-soluble or water-dispersible substance, and between about 16% and about 34% by weight of the film-forming resinous substance. The percent by weight of additives such as colorants, plasticizers, and waxy adjuvants in the new coating composition is quite small and usually does not exceed 10% by weight of the total amount of the coating composition.

The following examples are presented in order to describe the invention more fully, but it should be understood that the invention is not intended to be limited by these examples. In the examples, reference is made to a film-forming resin solution which is made up as follows:

10 g. of the resin named
4 ml. of propylene glycol
1 ml. of sorbitan monoolcate
40 ml. of alcohol
Acetone quantum sufficit to 100 ml.

The amount of the resin in such a solution is 10% w./v. and in the examples where it is stated that, for instance, 300 ml. of resin solution is used, it is to be understood that there will be 30 g. of the resin in the solution, or 10% w./v. The tablets referred to in the examples are convex shaped milk-sugar tablets made on a 5/16 inch punch. The coating liquid in all examples is used in an amount of approximately 100 ml. of coating fluid per pound of tablets.

EXAMPLE 1

A tablet coating solution is made up according to the following formula:

Poly(ethylene glycol)—6000	...		70 g.
Poly(methylstyrene), 10% w./v. solution	...	...	300 ml.
Acetone	...	...	q.s. to 500 ml.

The poly(ethylene glycol) is dissolved in a portion of warm acetone and is then added to the poly(methylstyrene) solution. The remainder of the acetone is added and the mixture is thoroughly stirred. The solution is applied to a rotating bed of tablets by pouring small portions onto the tablets. As the tablets rotate, the material distributes evenly over the surface thereof and in a few minutes' time the solvents evaporate, leaving a dry, hard film. Thereafter, a second portion of the above solution is applied in the same manner and subsequent coats are applied until a film of the desired thickness is obtained. Tablets coated in this manner are pleasing in appearance and disintegrate without delay, either water or in gastric juices.

By incorporating into the above coating solution 12 g. of a well-known disintegrator, even faster disintegration of the tablets can be achieved.

The foregoing formula contains about 14% w./v. of poly(ethylene glycol) and about 6% w./v. of poly(methylstyrene).

EXAMPLE 2

A solution suitable for coating tablets is prepared according to the following formula:

Poly(ethylene glycol) 4000	...	70.0	g.
Methylstyrene/acrylonitrile copolymers 10% w./v. solution		300	ml.
Yellow Dye D & C #11	...	0.5	g.
Acetone	... ...	q.s. to 500	ml.

The formula is made up in the manner described in Example 1 except that the yellow dye is added to a portion of the acetone prior to thoroughly mixing the solutions. Tablets coated with 10—20 coats of this solution give a very pleasing yellow appearance, and are much smaller than identical tablets which have undergone subcoating and sugar coating of the standard tableting procedure.

EXAMPLE 3

A solution suitable for use in coating tablets is prepared according to the following formula:

Poly(ethylene glycol)—20,000		70.0	g.
Poly(vinyl chloride) 1% w./v. solution	...	300	ml.
Castor oil	... ...	1.25	g.
Acetone	... ...	q.s. to 500	ml.

This solution is made up an applied to tablets in the same way as described in Example 1. The film applies to the tablets very evenly with suitable distribution on the sides, edges and face of the tablets. A few

coats of the foregoing solution gives a film of approximately 60 microns in thickness and provides a suitable, tasteless and pleasing film about the tablet core.

EXAMPLE 4

A solution for use in coating tablets is prepared for use in the following formula:

Poly(ethylene glycol)—4000 ...	70.0	g.
Poly(vinyl butyral) resin, 10% w./v. solution... ...	300	ml.
Beeswax	5.0	g.
Acetone	q.s. to 500	ml.

This solution is prepared similarly to the preceding solutions except that the beeswax is dissolved in acetone by heating the acetone to about 50° C. When the acetone cools, the beeswax may come out in a very fine suspension which, however, does not alter the characteristics of the film. The film obtained on tablets in the manner described in the above examples is smooth and even and deposits uniformly on the sides, edges and faces of the tablet.

EXAMPLE 5

The following solution for coating tablets is made up:

Poly(ethylene glycol)—6000 ...	70.0	g.
Rosin-based semialkyd (acid No. 78, softening point 118°) 10% w./v. solution ...	300	ml.
Yellow Dye D & C #11 ...	0.5	g.
Castor oil	1.25	g.
Stearic acid	5.0	g.
Acetone	q.s. to 500	ml.

The poly(ethylene glycol) and the stearic acid are added to warm acetone and when the acetone has cooled somewhat, the yellow dye and castor oil are added thereto. The entire solution is mixed with the resin solution and thereafter applied to tumbling tablets in the customary coating pan. A portion of about 10 ml. of the solution is applied to about 2000 tablets and after about five minutes of tumbling time, the film formed is evenly distributed on all of the tablets and is substantially dried. Thereafter, another 10-ml. portion is applied and the same procedure is repeated until a coating of suitable thickness has been formed on the tablets.

EXAMPLE 6

The following solution is made up according to Example 5:

Poly(ethylene glycol)—6000 ...	100.0	g.
Terpene-modified alkyd resin (softening point 100—110°, specific gravity 1.24), 10% w./v. solution	350	ml.
D & C Red Dye #35 ...	100	mg.
Corn oil	1.25	g.
Cocoa butter	5.0	g.
Acetone	q.s. to 500	ml.

This solution is applied to tumbling tablets in the manner described in Example 5. In this example, 20% w./v. of waxlike substances and 7% w./v. of Petrex resin is contained in the coating fluid.

EXAMPLE 7

A solution suitable for application to tablets and the like to form a thin film thereon, is made up according to the following formula:

Poly(ethylene glycol)—4000 ...	100.0	g.
Methylstyrene/acrylonitrile copolymer, 10% w./v. solution	200	ml.
Green Dye D & C #1... ...	4.0	g.
Mineral oil	5.0	g.
Lanolin	5.0	g.
Acetone	q.s. to 500	ml.

This solution is prepared in the same manner as set forth in the preceding examples and differs therefrom in containing 20% w./v. of the water-soluble, waxlike material and 4% of the acrylonitrile/methylstyrene copolymer in solution.

EXAMPLE 8

A solution suitable for tablet coating is made up from the following ingredients:

Poly(ethylene glycol)—6000 ...	70.0	g.
Poly(methylstyrene), 10% w./v. solution ...	200	ml.
Orange Dye D & C #4 ...	250	mg.
Orange Lake D & C #17 ...	4.0	g.
Sesame oil	1.25	g.
Cetyl alcohol	5.0	g.
Acetone	q.s. to 500	ml.

The solution is made up in the manner set forth in the previous examples, differing in containing 14% w./v. of poly(ethylene glycol)—6000 and 4% w./v. of poly(methylstyrene) in the solution. The lake portion in the above color additives provides greater depth of color and superior covering power for the colorant in the solution than using the dye above.

EXAMPLE 9

A tablet coating solution is made up as in previous examples with the following components:

Poly(ethylene glycol)—6000 ...	70.0	g.
Poly(vinyl butyral resin, 10% w./v. solution ...	300	ml.
Red Lake D & C #3 ...	6.0	g.
Castor oil	1.25	g.
Beeswax	5.0	g.
Acetone	q.s. to 500	ml.

When applied to tablets, this solution provides a pleasing, glossy red color with strong covering power.

In a modification of this example, the Red Lake D & C #3 is substituted with 3 g. of red iron oxide pigment. Tablets coated with such a modified composition show a dull red color, also with very good covering power.

EXAMPLE 10

A solution for coating tablets is prepared according to the following formula:

Poly(ethylene glycol)—4000 ...	100.0 g.
Rosin-based semialkyd with an acid No. of 135—45 and a softening point of 123—38° C., 10% w./v. solution ...	5.0 g.
Vinyl stearate	5.0 g.
Acetone	q.s. to 500 ml.

In this solution the vinyl stearate is employed as an anti-sticking agent. The film obtained on tablets according to the method in the foregoing examples is smooth and even and deposits uniformly on the sides, edges and faces of the tablets.

EXAMPLE 11

The following ingredients are used to make a coating solution:

Poly(methylstyrene)	30.0 g.
Propylene glycol	9.34 g.
Sorbitan monooleate ...	3.0 g.
Ethyl alcohol, 200 proof ...	115.65 g.
Dye Yellow D & C, Lake #5	15.0 g.
Titanium dioxide	10.0 g.
Saccharin sodium	0.5 g.
Ethyl vanillin	2.0 g.
Poly(ethylene glycol)—6000 ...	70.0 g.
Acetone	q.s. to 500 ml.

The poly(methylstyrene) is dissolved in 100 ml. of acetone and to this mixture is added the propylene glycol and the sorbitan monooleate. The yellow dye, titanium dioxide, and the flavoring agent are added to a ball mill and sufficient acetone is added to cover the balls. After milling for 24 hours, the milled ingredients are added to the previous mixture. The poly(ethylene glycol) is melted in a portion of the alcohol and is then added to the previously composed mixture, together with the remainder of the alcohol. Acetone is subsequently added to bring the solution to a total volume of 500 ml. Before using this solution, its volume is tripled by adding 1000 ml. of acetone. This solution is pre-warmed to 45—50° C. and placed in the supply chamber of an air-suspension coater of the type described by Singiser and Lowenthal in the Journal of Pharmaceutical Sciences, Volume 50, page 168 (1961) or earlier publications to which that paper refers. A batch of 6.8 kg. of convex-shaped milk-sugar tablets made on a $^{5}/_{16}$-inch punch is coated with the said pre-warmed coating solution. The latter is applied at such a rate that the temperature of the air leaving the coating chamber does not fall below 26.5° C. The coating solution is applied in approximately 15 minutes and distributes evenly on the tablets. An elegant, yellow, uniformly distributed, glossy tablet coating is obtained.

In the foregoing examples it has been demonstrated that elegant coatings can be obtained on tablets with coating solutions containing, as essential ingredients, from about 14—20% w./v. of a hard, water-soluble or water-dispersible, waxlike resin and about 4—7% w./v. of a film-forming resin selected from the group consisting of poly(methylstyrene), methylstyrene/acrylonitrile copolymers, poly(vinyl butyral), poly (vinyl chloride), pentaerythritol or alkyd esters of rosin or modified rosins, and terpene-based alkyd resins, and an organic solvent system with a boiling point below 85° C. All of these film-forming resins are characterized in that they are water-insoluble, and highly resistant to climatic effects such as high humidity and/or temperature. The film-coatings produced with these coating compositions are chemically inert, e.g. they will not interact with the tablet core they cover; they do not deteriorate on long standing, thus increasing the shelf-like of tablets so coated; they provide a complete covering over tablets even from very dilute coating solutions; they cover tablet edges and corners even with very thin film dimensions; they are easily plasticizable; they are compatible with waxlike, hard, water-soluble components like poly(ethylene glycol) and may be applied to tablets by dip coating, conventional solution coating in coating pans, by air suspension coating, and other methods known in the tableting art. The selection of these film-forming polymers produces tablet coatings which will disintegrate rapidly in the digestive tracts of warm-blooded animals, providing fast access of gastric juices to the tablet core, yet protecting the patient from getting any taste perception from the tablet core. The coating produced may be glossy, colored or dull dependent on formulation variations, and the tablets so coated are substantially smaller and lighetr than those coated by standard sugar coating.

WHAT WE CLAIM IS:—

1. A coating composition for tablets, the coating composition containing as essential ingredients:

(a) A physiologically acceptable substance selected from poly (ethylene glycol), glyceryl monostearate and diglycol stearate,

(b) A film forming resin selected from poly

(methylstyrene), methylstyrene/acrylonitrile copolymers, poly (vinyl butyral), poly (vinyl chloride), pentaerythritol and alkyd esters of rosin, pentaerythritol esters of modified rosins, and terpene-modified alkyd resins; and

(c) An organic solvent system boiling below 85° C.

2. A coating composition according to Claim 1 wherein the said physiologically acceptable substance is present in an amount of from 14 to 20% weight for volume and the film forming resin is present in an amount of from 4 to 7% weight for volume.

3. A coating composition according to Claim 1 or Claim 2 wherein the physiologically acccptable substance is poly (ethylene glycol).

4. A coating composition according to any of the preceding claims wherein the film forming resin is poly (methylstyrene).

5. A coating composition according to any of Claims 1 to 3 wherein the film forming resin consists of a methylstyrene/acrylonitrile copolymer.

6. A coating composition according to any of Claims 1 to 3 wherein the film forming resin consists of a poly (vinyl butyral) resin.

7. A coating according to any of Claims 1 to 3 wherein the film forming resin consists of a rosin-based semialkyd resin.

8. A coating composition according to any of Claims 1 to 3 wherein the film forming resin consists of a terpene-based alkyd resin.

9. A tablet having as a coating material a thin film of a plastic coating composition consisting essentially of the water-permeable combination of a physiologically acceptable substance selected from poly (ethylene glycol), glyceryl monostearate and diglycol stearate and a film-forming resin selected from poly (methylstyrene), methylstyrene/acrylonitrile copolyers, poly (vinyl butyral), poly (vinyl chloride), pentaerythritol and alkyd esters of rosin, pentaerythritol esters of modified rosins, and terpene-based alkyd resins.

10. A tablet according to Claim 9 wherein the said physiologically acceptable substance is present in an amount of from 14 to 20 parts by weight and the film forming resin is present in an amount of from 4 to 7 parts by weight.

11. A tablet according to Claim 9 or Claim 10 wherein the said physiologically acceptable substance is a poly (ethylene glycol).

12. A tablet according to any of Claims 9 to 11 wherein the film forming resin consists of poly (methylstyrene).

13. A tablet according to any of Claims 9 to 11 wherein the film forming resin consists of a methylstyrene/acrylonitrile copolymer.

14. A tablet according to any of Claims 9 to 11 wherein the film forming resin consists of poly (vinyl butyral) resin.

15. A tablet according to any of Claims 9 to 11 wherein the film forming resin consists of poly (vinyl chloride).

16. A tablet according to any of Claims 9 to 11 wherein the film forming resin consists of a terpene-based alkyd resin.

17. A tablet having as a coating material a thin film of a plastic coating composition consisting essentially of 14 to 20 parts by weight of a poly (ethylene glycol) with a melting point of at least 45° C., and 4 to 7 parts by weight of a pentaerythritol ester of a rosin.

18. The fluid coating composition according to Claim 1 essentially as hereinbefore described.

19. A tablet coating composition substantially as described in any of the foregoing Examples.

20. A tablet coated with a composition substantially as described in any of the foregoing Examples.

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